THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PIETRO LA GRECA

Appeal No. 1997-1987
Application No. 08/108,005

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

I. This is an appeal from the final rejection of claims 13 through 18 and 22 through 26, all the claims remaining in the present application.

II. Background

Frequently, patients infected with the Human Immunodeficiency Virus (HIV) have accompanying neurological

complications. This is manifested by demyelination, in the form

of multifocal progressive leukoencephalopathy. Symptoms range from slight psychic disturbance to a clear neurological syndrome. Approximately ten percent of AIDS patients show serious neurological symptoms (aphasia, ataxia, areflexia, including paralysis and loss of sphincteric control); and in sixty-two percent of HIV-positive subjects, organic mental disturbances are described leading to alteration of the cognitive functions and to dementia. Specification, page 1, line 14, to page 2, line 3. The literature has reported that HIV-positive patients with accompanying neurological complications can exhibit deficiencies in 5-methyl-tetrahydrofolate (MTHF) and S-adenosylmethionine (SAMe). Specification, page 2, lines 3-5. Data from the literature suggest that deficiencies in MTHF and SAMe can be the cause of neurological degeneration in AIDS patients. Specifica-tion, page 2, line 16, to page 3, line 3. Administration of methionine and betaine has been suggested to correct these metabolic deficiencies. R. Surtees et al., The Lancet, vol.

335, March 1990. Specification, at page 3, lines 4-5. However, appellant has found that administering methionine and betaine at doses of 6 g/day for 14 days was not able to significantly increase MTHF and SAMe body fluid levels. Specification, page 3, lines 6-8.

III. Representative claims

Claims 15, 17, 22, and 23 are illustrative of the subject matter on appeal and read as follows:

22. A therapeutic method for treating neurological affections [sic] selected from the group consisting of subacute encephalitis associated with dementia and vacuolar myelopathies comprising administering to a patient in need thereof a therapeutically effective amount of at least one member selected from the group consisting of S-adenosyl-methionine salt, 5-methyltetrahydrofolic acid and 5-formyltetrahydrofolic acid.

15. A therapeutic method according to claim 22, wherein the S-adenosylmethionine is administered at doses ranging from 100 and 2000 mg/day.

17. A therapeutic method according to claim 22, wherein 5-methyltetrahydrofolic acid or 5-formyltetrahydrofolic acid is administered at doses ranging from 20 and 200 mg/day.

23. A therapeutic method according to claim 22, wherein the S-adenosyl-methionine salt is administered at the same

time or at close intervals with 5-methyltetrahydrofolic acid or with 5-formyltetrahydrofolic acid.

IV. References

The references relied on by the examiner are:

Le Grazie 5,059,595 Oct. 22, 1991

Surtees et al. (Surtees), "Central-nervous system methyl-group metabolism in children with neurological complications of HIV infection," The Lancet, vol. 335, pp. 619-621 (1990).

V. Rejections

The claims stand rejected as follows:

Claims 17, 18 and 22 under 35 U.S.C. § 102(e) as anticipated by Le Grazie.

Claims 13 through 18 and 22 through 26 under 35 U.S.C. § 103 as unpatentable over the combined teachings of Le Grazie and Surtees.

VI. Discussion

A. Rejection of claims 17, 18 and 22 under 35 U.S.C. § 102(e) as anticipated by Le Grazie.

1. The claimed subject matter is drawn to a therapeutic method for treating neurological afflictions selected from the

group consisting of subacute encephalitis associated with dementia and vacuolar myelopathies. The method comprises administering to a patient in need thereof a therapeutically effective amount of at least one member selected from the group consisting of S-adenosyl-methionine salt, 5-methyltetrahydrofolic acid and 5-formyltetrahydrofolic acid.

2. Anticipation under 35 U.S.C. § 102 requires a prior art reference to disclose each and every element set forth in the claims. See RCA Corp. v. Applied Digital Data System, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

3. Le Grazie discloses a therapeutic method for treating organic mental disorders, in particular senile and presenile primary degenerative Alzheimer dementia and multiinfarctual dementia. The method comprises orally administering a therapeu-tically effective amount of 5-methyl-tetrahydrofolic acid or 5-formyl-tetrahydrofolic acid or a pharmaceutically acceptable salt thereof in a controlled release form. Le Grazie, col. 1, lines 11-21, col. 2, lines 7-46. However, Le Grazie does not disclose treating a patient afflicted with

subacute encephalitis associated with dementia or vacuolar myelopathies.

4. In the Brief, pages 8 through 11, appellant argues that there are significant distinctions between the organic mental disorders described by Le Grazie and "subacute encephalitis associated with dementia and vacuolar myelopathies" recited in claim 22. Appellant argues that Le Grazie is directed to treating neuro-degenerative pathologies, whereas the claimed therapeutic methods are directed to treating pathologies "having a completely different origin." Brief, page 8, line 15, through page 9, line 7; and page 9, lines 20-23. Appellant further argues that senile or presenile dementia caused by Alzheimer's disease and multiinfarctual dementia have a different etiology than dementia caused by encephalitis. Brief, page 10, lines 1-9. The Rule 132 Declaration of Pietro Monaco, Paper No. 21, filed 10 April 1995, defines subacute encephalitis as "inflammation of the

brain," and vacuolar myelopathy as "a disease of the spinal cord." According to Monaco, dementia associated with subacute

encephalitis is caused by an inflammatory state of the brain; in contrast, senile or presenile dementia caused by Alzheimer's disease is characterized by diffuse cerebral cortical atrophy, and microscopically by the presence of argyrophil cells, loss of neurons, and neurofibrillary tangles. Monaco states that multiinfarctual dementia is generated by the presence in the brain of a series of infarcts (localized circumscribed areas of ischemic tissue necrosis, due to inadequate blood flow), and cannot be considered equivalent to dementia associated with encephalitis.

5. The examiner argues that "appellant's encephalitis associated with dementia and of vacuolar myelopathies is inherently encompassed in the dementia of the reference, especially in the absence of evidence to the contrary." Answer, page 4, lines 8-11. However, the examiner fails to provide a basis in fact or technical reasoning which would reasonably support the determination that encephalitis associated with dementia and vacuolar myelopathies are inherently disclosed by Le Grazie. See Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), and cases cited therein.

The examiner admits that the etiology of dementia caused by encephalitis differs from that caused by Alzheimer's disease, as shown in the Monaco declaration. However, the examiner states that "appellant has not conclusively shown the experimental evidence, so that the two phenomena can be distinguished." Answer, page 4, lines 22-23.

The examiner does not provide facts or scientific reasoning which would cast doubt on statements in the Monaco declaration that senile or presenile dementia caused by Alzheimer's disease and multiinfarctual dementia have a completely different pathology from dementia caused by encephalitis.

On this record, the examiner has not shown that treating patients afflicted with subacute encephalitis associated with dementia or vacuolar myelopathies by administering 5-methyl-tetrahydrofolic acid or 5-formyl-tetrahydrofolic acid is described by or inherently flows from Le Grazie.

Accordingly, we reverse the examiner's decision rejecting claims 17, 18 and 22 under 35 U.S.C. § 102(e) as anticipated by Le Grazie.

B. Rejection of claims 13 through 18 and 22 through 26 under 35 U.S.C. § 103 as unpatentable over the combined teachings of Le Grazie and Surtees.

1. To establish prima facie obviousness of the claimed subject matter, all the claim limitations must be taught or suggested by the prior art. See In re Royka, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

2. For the reasons previously set forth, Le Grazie fails to disclose treating a patient afflicted with subacute encephalitis associated with dementia or vacuolar myelopathies. Surtees discloses that levels of S-adenosylmethionine and 5-methyl-tetrahydrofolate in the cerebrospinal fluid (CSF) of children afflicted with subacute HIV encephalitis and neurological complications are lower than those determined in a reference population of children. Low levels of S-adenosylmethionine and 5-methyl-tetrahydrofolate demonstrate defective methyl-group metabolism, which Surtees suggests may be related to the neurological damage in HIV infection. Surtees, page 619, paragraph bridging cols. 1 and 2; page 621, first full paragraph; Fig. 1. Though Surtees

suggests that treatment with methyl-group donors such as betaine and methionine could be useful in HIV infection if the role of defective methyl-group metabolism is confirmed, nevertheless, Surtees does not disclose or suggest treating children with HIV-encephalitis by administering

S-adenosylmethionine salt or 5-methyl-tetrahydrofolic acid, as recited in claim 22. Accordingly, Surtees does not make up the deficiencies of Le Grazie, and we reverse the examiner's decision rejecting claims 13 through 18 and 22 through 26 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Le Grazie and Surtees.

VII. Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we reverse the examiner's decision rejecting claims 13 through 18 and 22 through 26.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
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WILLIAM F. SMITH	) APPEALS
Administrative Patent Judge	) AND
	) INTERFERENCES
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